UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA, *et al.*, *ex rel.* URI BASSAN

Plaintiffs,

v.

OMNICARE, INC.,

Defendant.

_____X 15 Civ. 4179

UNITED STATES OF AMERICA,

Plaintiff,

v.

OMNICARE, INC. and CVS HEALTH CORP.,

Defendants.

_____X

DECISION AND ORDER GRANTING IN PART AND DENYING IN PART THE GOVERNMENT'S AND DEFENDANTS' *DAUBERT* MOTIONS; DENYING DEFENDANTS' MOTION TO STRIKE; DENYING THE GOVERNMENT'S AND DEFENDANTS' MOTIONS TO SEAL; AND SETTING TRIAL SCHEDULE

McMahon, J.:

A total of eleven *Daubert* motions, accompanied by numerous motions to seal, have been filed in this trial-ready *qui tam* False Claims Act ("FCA") action, which was originally brought in June 2015 by relator Uri Bassan on behalf of the federal government, 29 states, and the District of Columbia against Defendant Omnicare, Inc., a long-term care ("LTC") pharmacy. In 2019, the United States (the "Government") intervened in the action, filing a complaint against Defendants Omnicare and CVS Health Corporation.[1]

Relator and the Government allege that, between 2010 and 2018, Omnicare consistently dispensed prescription drugs to individuals living at long-term residential facilities that were not

[1] CVS Health Corp. completed its purchase of Omnicare in August 2015.

supported by valid prescriptions. Omnicare allegedly dispensed drugs based on prescriptions that had expired, had run out of refills, or were otherwise invalid. Although Omnicare is alleged to have dispensed the drugs illegally (i.e., without a valid prescription), Omnicare still submitted for reimbursement to several federal healthcare programs. These submissions for reimbursement are alleged to have contained false information in violation of the FCA. In total, the Government alleges that Omnicare dispensed drugs based on invalid prescriptions to potentially tens of thousands of individuals living at more than 3,000 residential facilities. Dkt. No. 17 ¶¶ 146, 149.

For the reasons outlined below, the motions are decided as follows:

1. Defendants' Motion to Preclude Testimony of W. Thomas Smith, Dkt. No. 495, is DENIED.

2. Defendants' Motion to Preclude Testimony of Mary Beth Landrum, Dkt. No. 488, is DENIED.

3. Defendants' Motion to Preclude Aspects of David Nace's Testimony, Dkt. No. 485, is DENIED.

4. Defendants' Motion to Preclude Aspects of Alfred Lee Meyer's Testimony, Dkt. No. 498, is DENIED.

5. Defendants' Motion to Preclude Aspects of Chad Hardy's Testimony, Dkt. No. 503, is DENIED.

6. The Government's Motion to Preclude Testimony of Vipul Kella, Dkt. No. 490, is DENIED.

7. The Government's Motion to Preclude Testimony of Sherry Pound, Dkt. No. 492, is DENIED.

8. The Government's Motion to Preclude Testimony of Bo Martin, Dkt. No. 501, is DENIED.

9. The Government's Motion to Preclude Testimony of Trenton Thiede, Dkt. No. 505, is DENIED.

10. The Government's Motion to Preclude Testimony of Barry Hart, Dkt. No. 508, is DENIED.

11. The Government's Motion to Preclude Testimony of Reginald Dilliard, Dkt. No. 510, is GRANTED IN PART AND DENIED IN PART.

12. Defendants' Motion to Preclude Margo Kunze's Late-Provided Declaration, Dkt. No. 483, is DENIED.

13. Finally, the parties' motions to seal and to maintain a seal are DENIED, subject to the provisions of this order.

***DAUBERT* MOTIONS**

The Government has made six *Daubert* motions and the Defendants have made five. As is generally the case, almost all of these motions were entirely unnecessary and a complete waste of the Court's time. With one partial exception they are all being denied – as they should be.

When expert testimony is offered, the district court serves a "gatekeeping" function in determining whether an expert witness really qualifies as one. Rule 702 provides that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

"The Second Circuit has distilled Rule 702's requirements into three broad criteria: (1) qualifications, (2) reliability, and (3) relevance and assistance to the trier of fact." *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. 5, 27 (S.D.N.Y. 2020).

The party proffering the expert's opinions "has the burden to establish the [Rule 702] admissibility requirements, with the district court acting as a 'gatekeeper' to ensure that the 'expert's testimony both rests on a reliable foundation and is relevant to the task at hand.'" *In re Pfizer Inc. Secs. Litig.*, 819 F.3d 642, 658 (2d Cir. 2016) (quoting *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007)). The Court need not "admit opinion evidence that is connected to the existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). In its evaluation, "the district court must focus on the principles and methodology employed by the expert, without regard to the conclusions the expert has reached or the district court's belief as to the correctness of those conclusions." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002).

Ultimately, the *Daubert* standard is a "flexible one," *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (1993), "and will necessarily vary from case to case," *Amorgianos*, 303 F.3d at 266. District courts have "broad discretion in the matter of the admission or exclusion of expert evidence." *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996) (quoting *Salem v. United States Lines Co.*, 370 U.S. 31, 35 (1962)). Even if an expert is qualified, the Court must still consider whether the probative value of the testimony is "substantially outweighed by a danger of . . . unfair prejudice" or likelihood of confusing or misleading the jury. Fed. R. Evid. 403; *see also United States v. Dukagjini*, 326 F.3d 45, 55 (2d Cir. 2003).

With that laid out, we turn to the eleven *Daubert* motions.

A. THE COURT DENIES DEFENDANTS' MOTION TO PRECLUDE TESTIMONY OF W. THOMAS SMITH.

This utterly frivolous *Daubert* motion is DENIED for the reasons set forth in the Government's Memorandum of Law in Opposition to the Motion, Dkt. No. 548, which the Court adopts *in toto* as its reasoning.

Particularly offensive is Omnicare's suggestion that because an eminently qualified licensed pharmacist and Professor of Pharmacology refers to state law in order to determine the requirements for dispensing controlled substances by pharmacists, he is "usurping the function of the court or jury." It is perfectly acceptable for someone who trains student pharmacists in how to apply state law in their everyday operations to explain how that process works, and to explain that pharmacists need to be conversant with state laws and are trained to understand those laws – even though they are not themselves licensed to practice law. One need not be a lawyer to be familiar with a particular area of law that is relevant to one's life's work. Moreover, as the Government points out, of the 45,544 dispensings identified by Dr. Smith and his team as invalidly prescribed, the vast majority – 31,392 dispensings – were dispensed with no prescription or medical authorization at all. It takes no law license to appreciate that dispensing controlled substances without any prescription at all would contravene the law in most if not all states. Dr. Smith, who trains pharmacists for a living, is particularly well equipped to explain to the jurors that any competent pharmacist would be expected to know that fact.

Dr. Smith's testimony would be helpful to the trier of fact. Dr. Smith is spectacularly well qualified to explain what it is that pharmacists are required to do in order lawfully to dispense controlled substances to patients, both in community and in LTC settings. And because he is fully familiar with those requirements – requirements that are likely not known to the trier of fact – he is equally equipped, by training and experience (including his experience managing an LTC pharmacy, which he did at the outset of his distinguished career), to examine dispensings and reach conclusions about whether Omnicare complied with core pharmacy standards in making those dispensings. The fact that Dr. Smith's testimony is adverse to Omnicare's position in this lawsuit is hardly a reason to exclude it, but this Court can only conclude, from the tenor of Defendants' motion, that it is precisely because the testimony is so damning that Omnicare is grappling for some reason to keep it out.

Defendants have failed to articulate any cognizable reason why Dr. Smith's testimony should not be admitted. To the extent Omnicare believes Dr. Smith's review of the dispensings to be inaccurate, it can handle the matter on cross examination or – as it proposes to do – through its own expert. *See infra*, Sections G-I. Any criticism of his credentials goes to the weight to be accorded his testimony.

B. THE COURT DENIES DEFENDANTS' MOTION TO PRECLUDE TESTIMONY OF MARY BETH LANDRUM.

For substantially the reasons set forth by the Government in its Memorandum in Opposition to Omnicare's *Daubert* motion, Dkt. No. 546, this motion is DENIED.

Dr. Landrum, a professor of Biostatistics at Harvard Medical School, is eminently qualified to perform the statistical analysis at the heart of her proposed testimony, and Omnicare does not challenge her qualifications or expertise. To the extent that Omnicare seeks to exclude her opinions because they are predicated on Dr. Smith's testimony, the Court's emphatic rejection of that meritless argument disposes of this ground for preclusion. Nor, as the Government explains in its brief, does Dr. Landrum's proposed testimony fail to fit with the Government's allegations in this case.

Omnicare's principal argument is that the type of statistical extrapolation performed by Dr. Landrum is not appropriate, because Dr. Smith's conclusions are patient, dispense, and state-law specific and so cannot be extrapolated to a wider universe. On the facts of this case, that dog won't hunt.

Statistical sampling is, in this case as in so many others, the only practicable means to collect and present relevant data that might establish a defendant's liability. *Tyson Foods, Inc., v. Bouphakeo*, 577 U.S. 442, 455 (2016). At page 6 of the Government's brief are listed numerous cases in which statistical sampling of the sort performed by Dr. Landrum has been relied on in FCA cases. The facts of these cases are not dissimilar to the facts of this case, suggesting that they are appropriate precedents to consider when evaluating the admissibility of her testimony.

By contrast, the cases on which Omnicare relies to suggest that statistical sampling is inappropriate in this case – because prescriptions are patient-specific and reliant for their validity on different state laws – are singularly inapposite, for fact-based reasons. For example, in *United States v. Vista Hospice Care, Inc.*, 2016 WL 3449833, at *11 (N.D. Tex. June 20, 2016), sampling was deemed unreliable because a patient's eligibility for hospice care is inherently subjective and depends on the clinical judgment of the patient's physicians. Here, by contrast, the alleged wrongdoing is the dispensing of controlled substances in accordance with a pre-programmed computer algorithm that was designed to do away with the need for any subjective analysis or judgment by individual doctors. The very thing that made sampling inappropriate in *Vista Hospice* is not present in this case.

The analysis performed by Dr. Smith, on which Dr. Landrum relies, was based largely if not entirely on the sort of criteria that are routinely used by pharmacy benefits managers ("PBMs") when conducting legally-required audits in order to assure themselves that valid prescriptions support claims for payment. There was no review of underlying patient medical records or any subjective clinical judgment calls. And the fact that different state laws apply to dispensings in different states is irrelevant, because Omnicare's computerized dispensing program does not vary by state, patient, facility or pharmacy within the sample population. The court in *Vista Hospice* acknowledged that statistical sampling and extrapolation might well be appropriate in such a case. *Id*. I conclude that it is indeed appropriate in this one.

Dr Landrum, like Dr. Smith, is eminently qualified to perform the analysis she performs and to offer the opinions she offers. Omnicare is free to cross examine her if it believes it can undermine her testimony. It cannot, however, exclude it.

C. THE COURT DENIES DEFENDANTS' MOTION TO EXCLUDE DR. DAVID NACE'S RISK OF HARM TESTIMONY.

Defendants move to exclude one portion of the proposed testimony of Dr. David Nace: his risk-of-harm opinion. That motion is DENIED.

In his expert report, Dr. Nace opines on the "risks of the dispensing of certain non-controlled drugs by Omnicare to patients in assisted living facilities." Dkt. No. 486-1, at 1. Defendants challenge Dr. Nace's risk-of-harm opinion on the grounds that it is inadmissible, *first*, because the opinion is unsupported by evidence on the record and, *second*, because the opinion is impermissibly speculative. Dkt. No. 486, at 5.

We can readily dispense with the first argument, which is meritless to the point of being frivolous. Dr. Nace's risk of harm analysis is amply supported by evidence on the record. It is based on a review of "data derived from the analysis of a sample of prescription files of Omnicare patients in this case." Dkt. No. 486-1, at 7, n.33. In *U.S. Bank Nat'l Ass'n v. PHL Variable Life Ins. Co.*, 112 F.Supp.3d 122, 131 (S.D.N.Y. 2015), the court stated that an "expert is permitted to rely on facts, opinions, and data not of the expert's own making—including analyses performed on findings made by another expert in the case." As in *PHL Variable Life,* Dr. Nace has analyzed the data set that was produced by Dr. W. Thomas Smith. Dkt. No. 486-1, at 8, 10. As has been seen, Defendants' equally frivolous motion to preclude Dr. Smith from testifying is being denied in its entirety.

Defendants' second argument, which is that Dr. Nace's opinion is impermissibly speculative, because the record is devoid of evidence that any of Omnicare's patients was actually harmed, merits more discussion.

"The fact that an expert witness speaks in probabilities, rather than certainties, does not by itself make the testimony inadmissible." *Deutsch v. Novartis Pharms. Corp.*, 768 F.Supp.2d 420, 437–38 (E.D.N.Y. 2011). However, as I understand it, the Government is not offering any evidence that any patient was actually harmed as a result of Omnicare's prescription renewal practices. Still, it might not take an expert for a trier of fact to conclude that there is some risk that a patient could be harmed if drugs are administered to him/her without a valid prescription.

Moreover, this is not a case like *Lynch v. Trek Bicycle Corp.*, 374 F.App'x 204, 206–07 (2d Cir. 2010), in which our Court of Appeals affirmed the district court's exclusion of an expert's speculation on how an event "could have happened." Dr. Nace is not being asked to opine on how unprescribed or invalidly prescribed drugs "could have" been issued to LTC patients. The underlying fact – Omnicare has a computer program that automatically refills a prescription when certain settings are enabled – is not disputed. The event that "could have happened" did happen;

medications were dispensed when "prescribed" in that manner. What is disputed is whether that is a valid prescribing practice. Dr. Nace is not opining on that.

That being so, the real question is not whether Dr. Nace's testimony about risk of harm (the only portion of his testimony that is under review here) is speculative – it is not – but whether risk of harm is something the Government is required to prove in order to make its case. I don't understand that it is. Therefore, I can see no reason why the Government should offer Dr. Nace's opinion on risk of harm in its case in chief. If I am mistaken about the relevance of this testimony to something the Government needs to prove, we can work that out at the final pre-trial conference.

However, if, as the Government anticipates, Dkt. No. 547, at 2, 10, Defendants call Dr. Kella to testify about risk of harm or a related issue that opens the door to risk of harm, this aspect of Dr. Nace's testimony would likely be highly relevant in rebuttal. For that reason, the motion to exclude Dr. Nace's risk of harm testimony is DENIED.

D. THE COURT DENIES DEFENDANTS' MOTION TO PRECLUDE ASPECTS OF TESTIMONY OF ALFRED LEE MEYER.

Defendants' motion to exclude aspects of Dr. Alfred Lee Meyer's testimony is DENIED for the reasons, again, set forth in the Government's Memorandum of Law in Opposition to the motion, Dkt. No. 545, which the Court adopts as its reasoning.

The Government offers Dr. Meyer to rebut the opinions of Defendants' experts that it was prevailing industry practice during the relevant period for pharmacies to dispense medications to individuals living in residential LTC facilities using chart orders that lacked quantity or refill information, and that did not expire.

Defendants challenge Dr. Meyer's qualifications to opine on such questions because Dr. Meyer "never has practiced pharmacy outside of California," Dkt. No. 545, at 2, and, therefore, does not understand the nuances to pharmacy practice in each state," *id*. at 3.

Defendants' challenge is unfounded. Dr. Meyer has ample experience: he has practiced in two national LTC facility chains in which he managed pharmacy services in numerous states and served as President of the American Society of Consultant Pharmacists. Defendants fail to persuade me that this is insufficient experience with which to understand state-to-state "nuances" to pharmacy practice. If Omnicare believes his credentials less than sufficient it can bring that out on cross and argue against the weight to be accorded his testimony. Of course, if Omnicare does so, it will be subject to a "what's good for the goose is good for the gander" argument from the Government, which correctly notes that two of Defendants' experts – Reginald Dillard and Barry Hart – opine on the very same questions without having practiced pharmacy in multiple states.

E. THE COURT DENIES DEFENDANTS' MOTION TO PRECLUDE ASPECTS OF TESTIMONY OF CHAD HARDY.

Defendants move to exclude certain aspects of the testimony of Chad Hardy, who opines on LTC-pharmacy-system design, computer system access, training, and computer manuals. Dkt. No. 504. This motion is DENIED.

The Government offers Hardy as an expert in computer dispensing systems. Specifically, the Government engaged Hardy to provide his expert opinion about the programming measures that Omnicare should have put in place to prevent prescriptions from improperly rolling over when drugs were dispensed to individuals in LTC facilities. Hardy also opines on Omnicare's failure to limit who had access to the computer settings that triggered rollover dispensing, Omnicare's failure to train staff on the rollover functionality, and Omnicare's failure to maintain adequate and current reference materials, which made it difficult for staff to understand and appropriately configure the rollover computer settings. Dkt. 517-8.

Defendants challenge aspects of Hardy's testimony on two grounds. *First*, Defendants contend that Hardy is not qualified to opine on LTC-pharmacy practice. *Second*, Defendants argue that Hardy's expert report includes "improper attempts to opine as to facts Hardy did not perceive," thereby rendering his opinions inadmissible. Dkt. No. 506, at 8.

With regard to Hardy's qualifications, Defendants argue that Hardy, while an experienced retail, inpatient and outpatient pharmacist, has no experience as an LTC pharmacist and is, for that reason, unqualified to offer expert testimony on the programming measures of an *LTC* pharmacy. I am not convinced. Hardy's opinions apply to any pharmacy that uses a computer system to enter prescriptions and track them over time. *See* Dkt. No. 517-8, at 4-6. As the Government notes, "Defendants do not suggest that Omnicare operated a bespoke mom-and-pop pharmacy that did not need such systematic controls," as would be common to any large-scale pharmacy operations. Dkt. No. 554, at 6; *see e.g. Stagl v. Delta Aire Lines, Inc.*, 117 F.3d 76, 82 (2d Cir. 1998). In short, Hardy is qualified; any deficit of experience is fodder for cross and goes to the weight of his testimony.

In the alternative, Defendants argue that Section IV of Hardy's expert report asserts that Omnicare's deviation from standard dispensing practices *caused* dispensing errors, though he is not a percipient witness and so allegedly cannot testify to whether these events occurred. Dkt. No. 506, at 1. This supposedly renders his opinions speculative, and hence inadmissible.

Again, I am not persuaded. Hardy opines on the measures Omnicare should have implemented to prevent prescriptions from *potentially* rolling over. He will not testify that the prescriptions *did in fact* roll over – that fact the Government will prove with other evidence. At the very least, Hardy's technical expertise could help the trier of fact determine whether Omnicare knew or should have known about the risk of improper rollover dispensing. I also trust that the Government will hold to its assurance that "[t]o the extent Hardy's report could be construed as Defendants suggest, the Government agrees that Hardy will not offer testimony that any prescriptions *did* improperly roll over or that any dispensations *did* occur without a current and valid prescription." Dkt. No. 544, at 2, n.2.

F. THE COURT DENIES THE GOVERNMENT'S MOTION TO PRECLUDE TESTIMONY OF DR. VIPUL KELLA.

The Government moves to preclude the proposed testimony of Dr. Vipul Kella. Dr. Kella's opinion is that chart orders are a medically-appropriate mechanism for doctors to prescribe on an ongoing basis and that such a mechanism minimizes risk to patients requiring uninterrupted long-term medication. The Government seeks to preclude the testimony of Dr. Kella on the bases that *first*, Dr. Kella is not qualified to offer expert testimony on residential care practices, *second*, Dr. Kella's opinions as to residential facility practices are not based upon sufficient facts or reliable methods, and *third*, Dr. Kella's opinions regarding medication adherence and chart orders generally would not assist the trier of fact to understand or determine any fact in issue. Dkt. No. 491. These arguments are as unpersuasive as Defendants' arguments against the admissibility of the testimony of many Government witnesses. Accordingly, this motion is DENIED.

Dr. Kella is qualified to offer expert testimony on residential care practices. Dr. Kella is an Emergency Medicine physician with over eighteen years of practice and ten years of hospital administration experience. Dkt. No. 517-11 ¶ 1. In his clinical experience, he has managed thousands of patients from assisted living facilities and skilled nursing facilities. *Id.* ¶ 2. He has also sat on hospital committees coordinating care between LTC facilities and hospitals. *Id.* ¶ 2.

Dr. Kella's opinions about patient care at assisted living facilities are reliable and based on sufficient information. The Government seeks to preclude Sections V and VI of Dr. Kella's report on the grounds that Dr. Kella's opinions are "based entirely on his review on general literature and surveys." Dkt. No. 491, at 6. But opinion testimony is not barred because it is based on a review of, or familiarity with, literature in the field; indeed, such familiarity often undergirds an expert's opinion. Moreover, Dr. Kella also grounds his opinion in his clinical and administrative experience. *See* Dkt. No. 517-11; *see also* Dkt. No. 533-1. Experts may "base[] testimony upon professional studies or personal experience." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Here, the Government may cross examine the witness and allow the finder of fact to make its own determination on the weight to afford Dr. Kella's testimony.

Dr. Kella's opinions regarding medication adherence and chart orders could prove helpful to the finder of fact. The Government argues that Section IV of Dr. Kella's report should be precluded because it may potentially mislead the finder of fact on the central issue in the case: namely, how chart orders should be used. Dkt. No. 491, at 8. However, this is simply a case of arguing, "Their expert does not agree with our expert (in this case, Dr. Nace), so you should preclude their expert from testifying." The Court is sick to death of receiving *Daubert* motions that, stripped to their essentials, make this ridiculous argument. Dr. Kella will explain why prescribers might choose to write a valid prescription by using a chart order rather than a retail prescription. Dkt. No. 517-11 ¶¶ 47–53. The Government argues that this may confuse the jury into thinking that the question at issue in the case is whether chart orders are ever valid, while this case centers on whether chart orders are valid for unprescribed medication. Dkt. No. 491, at 8. Any misapprehension on the factfinder's part can be cleared up by rigorous cross-examination on the Government's part, and does not require the Court to preclude Dr. Kella's testimony.

G. THE COURT DENIES THE GOVERNMENT'S MOTION TO PRECLUDE TESTIMONY OF SHERRY POUND.

The Government moves to exclude proposed expert testimony from Sherry Pound, Dkt. No. 492, a consultant with over 20 years of experience across the healthcare field, including work advising PBMs and health insurers through audits, reporting, and claim processing, Dkt. No. 515-1, at 1. The motion to exclude Pound's testimony is DENIED.

The Government offers what Defendants aptly describe as a "kitchen sink" or "smorgasbord" approach to challenging Pound's expert testimony. Dkt. No. 537, at 1, 4. To start, the Government argues at multiple points that Pound's testimony merely "stat[es] the obvious" in its references to the deferential relationship between the healthcare industry and one of its regulators, the Centers for Medicare & Medicaid Services ("CMS"), as well as the difference in error rates between Dr. Smith's review of sample prescription dispensings and CMS's Part D Prescription Drug Event Validation ("PEPV") audit. *See, e.g.*, Dkt. No. 493, at 1-2; 4-6; 7-8; 9-10. Although the Government claims that this information should be excluded as unhelpful to the trier of fact, in no case is Pound merely offering "obvious" information for its own sake. Rather, she is adding contextual facts that are necessary for the jury to understand the broader points made in her report. An expert is not required to throw the trier of fact into the deep-end of expert opinion and is instead welcome – in fact, encouraged – to explain facts "grounded in academic study and practical experience not available to the average layperson" to lay the groundwork for more complex elements of her testimony. *Hnot v. Willis Grp. Holdings Ltd.*, 2007 WL 1599154, at *2 (S.D.N.Y. June 1, 2007).

The Government argues that the Court should prohibit Pound from critiquing Dr. Smith's methodology or findings because Pound lacks experience advising pharmacies directly. Dkt. No. 493, at 8-9. However, Defendants are correct that it is Pound's experience participating in PEPV audits – against which she compares Dr. Smith's review – that qualifies her to offer an expert opinion. If the Government disagrees, its arguments go to the weight, not the admissibility, of her testimony.

Finally, the Government cites multiple examples where Pound allegedly impermissibly describes the intent, motive, or state of mind of a government agency, CMS. These include describing the agency's purpose in conducting PEPV audits, its understanding of certain facts, and its areas of focus or principal concern. Dkt. No. 493, at 6-7. Defendants counter that Pound was merely connecting deposition testimony of CMS witnesses to her informed understanding of industry response to PEPV audits. *See* Dkt. No. 537, at 6. If Pound confines her testimony to the permissible sort of comparisons described above and, as Defendants aver, "will not testify about CMS' 'intent,'" there is no basis to preclude her from testifying about these matters.

H. THE COURT DENIES THE GOVERNMENT'S MOTION TO PRECLUDE TESTIMONY OF BO MARTIN AND TRENTON THIEDE.

The Government moves to exclude proposed testimony from Defendants' rebuttal experts, Drs. Bo Martin and Trenton Thiede, whose reports respond to those submitted by the Government's experts, Drs. Landrum and Smith. Dkt. Nos. 501; 505. These motions are DENIED.

One of the Government's primary contentions is that Drs. Martin and Thiede are not lawyers and are therefore not qualified to offer opinions about the Government's legal argument or to testify as to how the Government's experts' reports do or do not relate to the underlying allegations in the Complaint. The Government cites to multiple instances across the reports where Drs. Martin and Thiede claim that the methods and analysis employed by Drs. Landrum and Smith, "may not align with the allegations in the Plaintiff's complaint," are "inconsistent with the issues outlined in the Complaint," and have "no connection to the Government's allegations." Dkt. No. 517-16, at 6, 22; Dkt. No. 517-6, at 3.

In response, Defendants claim that Drs. Martin and Thiede only seek to offer opinions on how "Landrum's samples and extrapolation . . . were not tailored to what Dr. Landrum said she was seeking to analyze," Dkt. No. 536, at 4, and how "Dr. Landrum and Dr. Smith failed to tailor their audit to what they set out to measure," Dkt. No. 540, at 5. If, as Defendants claim, Drs. Martin and Thiede will not offer impermissible legal opinions or veer into analysis of what is or is not comprehended by this lawsuit – something that no witness for either side will be allowed to discuss in my courtroom – the Government has no basis to preclude their testimony (remembering that no expert's report will be coming into evidence; they will testify in open court and their reports can be used only to cross examine). To the extent that these experts are criticizing the methodology of the Government's experts, or are opining that their data does not allow them to reach the conclusions they reach, they are offering classic rebuttal testimony.

Certainly Defendants' rebuttal experts are qualified to offer that sort of testimony. Dr. Martin is an accomplished statistician and has extensive expertise in the analysis of statistical models of the type conducted by the Government's experts in this case. Dkt. No. 517-16, at 3-4. This no doubt explains why the Government does not question Dr. Martin's credentials. Instead, its arguments amount to many different ways of saying that Dr. Martin's opinions differ from those of the Government's own experts. As I have repeatedly stated, that is no reason to preclude an expert's testimony.

Similarly, Dr. Thiede's resume includes a wealth of experience as a licensed pharmacist and involvement in over 101,000 audits across numerous types of pharmacies. Dkt. No. 517-6, at 1. Despite this overwhelming show of expertise, the Government argues that Dr. Thiede is not qualified to offer rebuttal testimony, because his experience is limited to "responding to audits, not conducting" them. Dkt. No. 520, at 5. That is an absolutely ridiculous argument – tantamount to similar arguments made by Omnicare at which the Government took umbrage. Dr. Thiede's work across thousands of pharmaceutical audits provides him with the knowledge and experience necessary to assist the trier of fact in this case. If the Government would like to try to undermine

his credentials on cross examination, it is free to do so. Its other arguments as to the reliability of Dr. Thiede's conclusions go to weight, not admissibility.

I. THE COURT DENIES THE GOVERNMENT'S MOTION TO PRECLUDE TESTIMONY OF BARRY HART.

The Government's motion to exclude aspects of the proposed testimony of Barry Hart is DENIED.

Defendants offer Hart to rebut aspects of the testimony of Dr. Smith and Hardy, and to opine that Omnicare's LTC pharmacy computer functionalities, practices, and training were not in line with industry standards of practice.

The Government challenges Sections IV.C, IV.D, and V (except for opinions concerning the application of Indiana pharmacy law) and portions of Sections VI.B, VI.C, and VI.D that discuss Omnicare's practices. The Government challenges this testimony on two grounds. The Government argues both that Hart lacks sufficient experience to provide his proffered opinions on state pharmacy law and industry practice, and that several of Hart's "opinions" are thinly disguised factual narrative. *See* Dkt. No. 519. Both challenges lack merit.

Hart has the requisite experience: thirty years of industry experience, eight years at PharMerica, an LTC pharmacy chain managing or working at LTC pharmacies across several states, as well as experience starting his own LTC pharmacy. The Government's critique of Hart's methodology is once again little more than "their expert doesn't agree with our expert." *In re Namenda Indirect Purchaser Antitrust Litig.,* 2021 WL 2403727, at *1 (S.D.N.Y. June 11, 2021).

Moreover, I am not persuaded that Hart's report includes inadmissible factual narrative about whether Omnicare's training and protocols allowed dispensing errors to occur. However, I note again that no expert report will be admitted. If testimony turns into factual narrative untethered to actual opinions, it will be stopped and/or stricken. But I remind the Government that its witnesses, too, offer opinions tethered to a particular understanding of the facts of the case – opinions that I have admitted into evidence. It is up to the Government to explain to the trier of fact that the view of the facts on which the expert relied in forming his opinion is incorrect – if it can do so with convincing evidence.

J. THE COURT GRANTS IN PART AND DENIES IN PART THE GOVERNMENT'S MOTION TO PRECLUDE TESTIMONY OF REGINALD DILLIARD.

Finally we reach a motion that has at least some modicum of merit.

The Government's motion to exclude the proposed testimony of Reginald Dilliard is GRANTED IN PART AND DENIED IN PART.

Defendants offer Dilliard to rebut the testimony of Dr. Smith and to opine on the role of boards of pharmacy and how pharmacists use their judgment to address ambiguous areas of pharmacy practice.

The Government challenges Dilliard's testimony on two grounds: that he has insufficient experience with LTC pharmacies to opine on the industry practices, and that his methodology is unreliable because he "proposes to testify that all state laws are so vague that the decisions of whether or how to comply with them are in the discretion of every LTC pharmacist." Dkt. No. 518, at 1.

The first challenge clearly goes to the weight and the Government is free to challenge the purported weakness of Dilliard's credentials on cross and in argument. While Dilliard may never have *practiced* in an LTC pharmacy, his testimony concerns the regulatory framework that governs practices in those pharmacies. Dilliard has decades of board-of-pharmacy and pharmacy-regulation experience. Those are not inherently insufficient credentials.

If Dilliard were actually proposing to testify that "all state laws are so vague that decisions about whether or how to comply with them are in the discretion of every LTC pharmacist," I would not permit him to testify. It goes without saying that no pharmacist, LTC or otherwise, has discretion to decide "whether" to comply with state law; any "expert" who claimed otherwise would not be permitted anywhere near a witness stand in my courtroom or any other. And while "how" to comply with state law is of course within a pharmacist's discretion, that discretion is constrained by the language of the statute, which would not permit certain "discretionary" decisions.

But the Government's description of Dilliard's opinions is too cute by half. He offers four opinions.

The first is that, because state law governs pharmacy practice, regulation is decentralized and lacks uniformity. There is nothing wrong with Dilliard's offering such an opinion, though I do not understand Dr. Smith's opinion on that score to be any different. To that extent, the Government's motion is denied.

Second, he opines that state pharmacy laws necessarily contain "gaps" because lawmakers cannot possibly imagine every situation that might confront a pharmacist, or that might arise as pharmacy practice changes with the times. He further opines that, in such circumstances, pharmacists must make professional judgments predicated on their understanding of both legal requirements and prevailing industry practice. Again, I see nothing wrong with Dilliard's offering such an opinion, and again I do not understand the Government's expert to disagree with it.

Third, and probably most significantly, Dilliard opines that state laws have not kept up with changes in prevailing pharmacy practice over the years, particularly during the Relevant Period, which in his view has created regulatory ambiguity that pharmacists are free to fill in with their own best pharmacological judgment. Now of course, if developing practices are not in accord with state law, pharmacists are not free to ignore the law in favor of what they consider best practices. Dilliard may not testify, to the extent he proposes to testify, that LTC pharmacists were free, in the

absence of amendments to state law, to substitute evolving industry norms (such as those of the National Association of Boards of Pharmacy ("NABP")) for restrictions found in state laws. If the law is out of date, the industry must lobby for its amendment; it is not free to ignore it. Dilliard may, however, testify that it was accepted practice to subscribe to evolving industry standards (such as NABP recommendations) in circumstances where state law on a particular point (in this case, the use of Chart Entries to prescribe medications) is silent.

Finally, Dilliard is perfectly free to opine that Dr. Smith misreads state law, and that his description of state regulatory schemes contains obvious errors or unwarranted extrapolations. What's good for the goose . . . But he may not testify that pharmacists are free to substitute industry standards for the requirements of the law. Because that is not the law.

OUTSTANDING MOTION TO STRIKE

Defendants' Motion to Preclude Margo Kunze's Late-Provided Declaration, Dkt. No. 483, is DENIED. Kunze's June 21, 2024 declaration, correcting testimony given at her October 17, 2023 deposition, will not be stricken, and her deposition testimony is deemed amended to incorporate the correction in her declaration.

Kunze and the Government attempted to correct an error in her testimony just one month after Kunze's deposition by filing an errata sheet, but Magistrate Judge Figueredo directed the Government to withdraw it on procedural grounds. I would not have done that, but it was done. After withdrawing the errata, Kunze submitted a two-page declaration to correct what she and the Government believed was a factual inaccuracy in her testimony. This led to Omnicare's motion to strike. That motion has not yet been decided. I am, therefore, disposing of it today.

The motion is denied, and the deposition testimony is deemed amended. Defendants' request that discovery be reopened is denied. Any questions that are needful as a result of the change in her testimony can be directed to her during the trial. End of story.

MOTIONS TO SEAL

Both the Government and Defendants seek permission to file certain items under seal as part of their motions. The parties wish to file these items under seal pursuant to the Protective Order entered by the Court on November, 29, 2021. Dkt. No. 102 (the "Protective Order").

The Protective Order ¶ 19, states:

> Before any party may file with the Court any pleadings, motions, or other papers disclosing information designated as Confidential Information by a Producing Party, such filing party shall make an application to the Court requesting that the papers disclosing information designated confidential be filed with redactions and under seal for a period of fourteen (14) days during which time the Producing Party may file a motion to seal such information….

The Government submitted three motions to seal. Dkt. Nos. 513, 522, 541. Defendants have not responded to any motion. Defendants, in turn, have submitted five motions to maintain a seal. The Government has not responded to Defendants' motions to seal. Both parties have filed under temporary seal the items they seek to seal permanently.

The public has a "qualified First Amendment right to access" to judicial documents and proceedings. *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119 (2d Cir. 2006). The public also has a "common law right of public access to judicial documents [which] is firmly rooted in our nation's history." *Id.* As the Second Circuit explains, this deeply rooted right is "based on the need for federal courts . . . to have a measure of accountability and for the public to have confidence in the administration of justice." *United States v. Amodeo*, 71 F.3d 1044, 1048 (2d Cir. 1995). Therefore, under both the common law and the First Amendment, "a strong presumption of access" attaches to judicial documents. *Lugosch*, 435 F.3d at 121. That presumption against public access can only be overcome if sealing "*is essential* to preserve higher values" and "*narrowly tailored to preserve that interest*." *Id.* at 120 (emphasis added). Therefore, a party seeking to file documents under seal has a heavy burden to demonstrate that there is some reason why the public should not have full access to all publicly filed documents.

The parties' motions to seal or maintain a seal are DENIED. The time for protective orders is over. We are on the eve of trial. The Court has denied virtually all of the *Daubert* motions, and will admit virtually all of the testimony to which the temporarily sealed items pertain. We do not seal evidence that comes in during a trial; there is, therefore, no need to seal these items any longer.

Instead, the parties are directed to provide the Court and the Clerk of Court, no later than Tuesday, January 21, with a list identifying which of the hundreds of exhibits they sought to seal relate to testimony of witnesses who are being permitted to testify. The referenced documents will remain sealed until that date. After January 21, I will direct the Clerk of Court to unseal any document on that list (and if no list is provided, I will direct the Clerk to unseal all documents that were the subject of the motions).

Unsealing is subject to the following caveat: if the parties are seeking sealing in order to protect confidential patient information (names, social security numbers, addresses), then the parties must REDACT that information from the publicly filed documents. Nothing in this opinion relieves the parties of the obligation to redact such information. But they only have a week to get done what should have been done long ago; by January 21, the Clerk must receive redacted documents that can be filed publicly.

If any document that is the subject of this motion relates solely to testimony the Court has excluded, the party must provide the Court with a one-page brief (separate briefs for each document) explaining why that document contains confidential information that should remain under seal. These briefs are also due on January 21. The number of such briefs (if any) should be vanishingly small, because the only thing I can locate in the record that is even arguably confidential is patient personal information. Certainly the challenged Omnicare computer program, as well as information about Omnicare's prescribing practices, cannot remain under seal as "trade secrets," because it will be impossible to try the case without explaining these matters to the trier of fact in a courtroom open to the public and the press.

I will post rulings on any such documents as soon as possible. As soon as I rule, anything that I do not agree to keep sealed will be immediately unsealed, again subject to redaction of patient personal information.

TRIAL SCHEDULE AND PRE-TRIAL PROCEEDINGS

And so we come to scheduling.

The trial of this matter will begin on March 17 or as soon as the criminal trial in *USA v. Mehdiyev et al.*, 1:22-cr-00438 concludes. The *Mehdiyev* trial is supposed to begin on March 10, and if it does, it will likely not conclude prior to March 17, which means the actual first day of trial may be pushed back for a few days. That said, you are on ready-for-trial status as of March 17.[2]

This early spring trial date is not negotiable. This case has been around for ten years. The Government took an unconscionable amount of time to assume its prosecution, and as a result neither my late lamented colleague Judge Keenan nor two excellent and diligent Magistrate Judges were able to get the parties to move things along speedily. The only way to end the case is to try it, and I intend to end it early this spring. Scheduling conflicts for lawyers or witnesses will not cause me to move the trial date. So clear your calendars now.

If the parties want to try to settle, you are free to use the good offices of James O'Neill, my permanent law clerk, who has successfully settled several similarly complicated *qui tam* cases in the past. Mr. O'Neill, who principally handles my criminal docket, has done no substantive work on this case, so he will bring fresh eyes to your differences. Alternatively you can use Judge Figueredo or anyone else you wish. But the trial will not be adjourned to accommodate settlement talks, so don't stop trial preparation in order to participate in settlement negotiations. Have separate trial prep and settlement teams if necessary. Do not use a settlement mediator whose schedule cannot accommodate the trial date.

In limine motions are due no later than January 31, with responsive papers due on February 7. I do not accept replies on *in limine* motions. I remind the parties that *in limine* motions are NOT summary judgment motions; I will deny any motion that seeks the equivalent of summary judgment disposing of any open issue in this case. *In limine* motions are limited to evidentiary issues not covered by the *Daubert* decision. A separate motion must be made for each individual ruling sought. The motion must be supported by a brief of no more than five double-spaced pages, in 12-point type, with no footnotes. Any response is similarly limited to five double-spaced pages, in 12-point, type with no footnotes. Again, NO REPLIES will be accepted; I cannot state this strongly enough. I will issue a brief, written ruling granting or denying these motions at some point prior to the final pre-trial conference, which will be on Thursday, February 27, at 10 AM, in Courtroom 24A in the Moynihan Courthouse.

Proposed *voir dire* and jury instructions are due by the date of the final pre-trial conference.

[2] In case anyone might have been thinking about making a motion for summary judgment, don't bother. There are obvious genuine issues of material fact that must be tried. You are either going to try this case or settle it – now.

At the final pre-trial conference we will go over the parties' lists of witnesses. Each side will have no more than 20 hours for a combination of opening statements, closing statements and witness directs. Be selective. You will need to tell me how long you expect each witness to testify on direct at the final pre-trial conference.

At the final pre-trial conference I will also rule on the parties' objections to the introduction of exhibits. This, I find, saves a great deal of time at the actual trial. I suggest that the parties locate the no more than 200 (fewer if possible) key exhibits that they are really going to use with the jury during this trial and focus on those; we all know that the parties are not going to call thousands of exhibits to the jury's attention. We will go exhibit by exhibit and I will rule on any objections. Please understand that if one side chooses to object to each and every exhibit, or to most exhibits, or objects on multiple silly grounds to the introduction of the key exhibits in this case, I will conclude that your objections are not serious and will simply overrule them and admit all of your opponent's exhibits into evidence. In my experience far too many games are played with objections; I am only prepared to consider serious ones, and anyone who objects to all or most of his opponent's exhibits is not, in my book, being serious.

CONCLUSION

This omnibus opinion disposes of the parties' outstanding *Daubert* motions and motions to seal or maintain a seal. The Clerk of Court is directed to remove the motions at Docket Nos. 483, 485, 488, 490, 492, 495, 498, 501, 503, 505, 508, 510, 511, 513, 522, 526, 528, 531, 541, and 549 from the Court's list of open motions.

This constitutes the decision and order of the Court. It is a written decision. Please note: This opinion is NOT being filed under seal.

Dated: January 10, 2025

U.S.D.J.

BY ECF TO ALL COUNSEL